

Atty. Docket No. 25668

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Dated: March \_\_, 2006

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: CHERUKURI, S. Rao

Attorney Docket: 25668

Filing Date:

Examiner: Coe, S

Serial No.:

Group Art Unit:

Title: Sugar-free Chew

Commissioner for Patents  
Washington, D.C. 20231

## DECLARATION OF S. Rao CHERUKURI UNDER 37 C.F.R. § 1.132

I, S. Rao CHERUKURI, citizen of United States of America, hereby declare that:

1. I have a Bachelor of Pharmacy and a Master of Pharmacy degrees, both from Andhra University, India, and an MBA from University of Pennsylvania, Wharton School of Management. My career in the United States started in 1973 as R&D Manager with Philadelphia Chewing Gums Corporation, Haverton, PA. From 1978 to 1981, I worked as Senior Research Manager, R&D at B.R. Squibb/Life Savers Corporation. In 1981 I joined Warner Lambert & Company and was their Director of Worldwide Technology Development when I left in 1991. I joined Fuisz International, Chantilly, VA in 1992 as Senior Director of Technology and held several progressively senior research and management positions and became President, Consumer Healthcare division. I left Fuisz in 2000, and founded Capricorn Pharma Inc., in Frederick, MD to develop innovative technologies in pharmaceutical, confectionary and nutraceutical businesses. My curriculum vitae is set forth in Appendix A to this Declaration. Over the years, from 1978 till to-date, my work (as a sole inventor or as a co-inventor) resulted in issuance of about one hundred United States patents including several international counterparts. Please see

Appendix B for a list of my issued U.S. patents. In view of the above, I believe that I am one of skill in the art in the subject matter of the above-identified application and in matters raised in the prosecution of the application, including matters relating to chewing gums.

2. I have read the subject application papers and the Office Action issued November \_\_, 2005. I am aware of the issues raised by the Patent Office in the previous and pending Office Actions, and in particular the references of record, \_\_\_\_\_ (hereinafter, "Patent").
3. All experiments disclosed in this Declaration were designed by me and were conducted by myself at Capricorn Pharma.
4. The experiments as disclosed in the present Declaration were conducted to compare certain characteristics of the presently claimed sugar-free soft chewy compositions with compositions that are generally known in the art as sugar-free chewing gums. As recited in the now pending claims, the claimed sugar-free chewy compositions are distinguishable from art-known sugar-free chewing gums at least in the characteristic of reheatability. Accordingly, the present experiments are designed to show that upon reheating of an already formed sugar-free base, the claimed compositions are distinct and possess desirable characteristics such as resiliency, compared to art-known sugar-free chewing gum bases.
5. I have collected four different commercially available sugar-free chewing gum compositions. These are: Cadbury's Trident Tropical Twist Sugarless Gum; Wrigley's Orbit Sugar-free Gum; Wrigley's Eclipse Polar Ice Sugarfree Gum; and Wrigley's Extra Polar ice Sugarfree Gum. These compositions are labeled as Reference Samples 1-4. To compare with these Reference Samples, I have used pre-formed sugar-free compositions prepared according to Example 8 of the current specification.
6. I have unwrapped the art-known compositions and placed a cut piece of 7/8 inch by 1/2 inch with 1/4 inch thickness of each of these compositions individually in 3 inch diameter Petri dishes. I have taken a square-shaped sugar-free composition of the present invention

and cut it laterally to obtain a cross section of the composition (hereinafter "Test Sample") that is matching in shape, size and weight with the art-known pieces placed in the Petri dishes. I have placed this Test Sample in a separate Petri dish.

7. The five Petri dishes (four Reference Samples and one Test Sample) were placed on a hot plate with gradual heating system. The temperature was allowed to rise and the temperature was measured in each Petri dish. It was observed that each Petri dish was being heated at the same rate.
8. I have observed that when the temperature was about 68-70 °C, each of the Reference Samples showed signs of deformation and lost its shape and texture as the heating continued.
9. In contrast, the Test Sample did not show signs of deformation at about 68-70 °C, and even when the temperatures were allowed to continue to rise and reached to 80 °C. The only observable change was a slight softening of the surface.
10. After noting the above, I have discontinued heating and let the compositions return to room temperature. The consistencies of the samples were noted at room temperature. The Reference Samples remained as a deformed gummy mass, have lost their malleability, and could not be formed into any coherent shape even with significant effort. The Reference Samples thus were not resilient. In fact, the mass in each Reference Sample Petri dish was stuck to the bottom of the dish and could not be removed, even for cleaning purposes. These Petri dishes were discarded and could not be reused.
11. In contrast, the Test Sample was not deformed and retained its shape. Even after returning to room temperature, the Test Sample retained its malleability. Thus, the Test Sample retained its plasticity and with simple manipulation with a spatula, I was able to form the mass into its original square shape. There was no sticking to the bottom of the beaker and the reheated re-formed Test Sample was removable with a simple tilting of the Petri dish.

12. From the above, it is very clear to me that the claimed compositions are distinct from the art-known sugar-free chewing gum compositions, at least for the reason that the former are reheatable which, upon reheating are capable of being formed into a soft chewy composition of desirable shape and size.
13. As stated in the specification, this unique characteristic of reheatability has practical industrial advantages: a) the composition is resistant to heat changes during manufacture, storage, transfer, and usage; b) the composition permits addition of thermolabile actives at a later point in the manufacture, and at a later time, such as upon shipping distant locations (including national and international locations), without reformulation of the base. As shown in the present experiment, the claimed compositions do not stick to manufacturing components upon reheating and are malleable. These are significant and distinct advantages compared to art-known compositions, including art-known sugar-free chewing gum compositions.
14. In addition, the soft-chew sugar-free compositions are distinct from chewing gum in at least one other aspect, namely, residual mass upon chewing. While the art-known chewing gum is meant for chewing and then spitting out the gum base after repeated masticating, and is swallowable in the sense that there is no practical harm for the person if swallowed, they nevertheless are designed to leave a mass for discarding after repeated masticating. In contrast, the present claimed soft-chew sugar-free compositions do not leave a residual mass for discarding upon repeated mastication. The present compositions are designed to disintegrate into smaller pieces in the oral cavity which then disintegrate further and dissolve either in the oral cavity or in the gastrointestinal cavity.
15. For the reasons stated above, I believe I have invented a unique soft-chew sugar-free composition for delivery of active agents and that such compositions are distinguished from the art-known compositions including sugar-free chewing gums.
16. I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of

the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date:

22nd March 2006



S. Rao CHERUKURI

5

Declaration of S. Rao CHERUKURI  
Under 37 C.F.R. § 1.132  
U.S. Serial No.: 10/024,583

## Appendix A

### CURRICULUM VITAE OF S. Rao CHERUKURI

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Vienna VA 22182

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Cell: 703- 932- 3840

#### Experience

##### **Capricorn Pharma Inc. Founder, President and CEO**

4/2000 to present  
Frederick, MD

Negotiated purchase of Capricorn facility from original owner, Aspen Holdings (South Africa), built management team and board, raised capital and managed all aspects of operations to date.

- Assembled management team with over 100 years of combined pharmaceutical experience and over hundred US and a multitude of international patents
- Raised debt and equity funding to meet working capital needs and fund additional capital investment in the facility
- Developed 5 products based of 16 proprietary technologies with 3 patents approved and 14 more pending
- Negotiated encapsulation supply contracts with leading European confectioners and trial plans with leading U.S. pharmaceutical firms
- Negotiated strategic partnership with a major Indian pharmaceutical firm to gain low cost access to their "specialty" generic R&D pipeline

##### **Biovail Corporation/Fulsz Technologies Ltd. Chantilly VA 22182**

11/92 to 3/00

President, Consumer Healthcare Division 7/98 to 3/00

Executive Vice President, Food and Nutraceutical Division

4/97 to 6/98

Sr. Vice President, Food Division

7/95 to 3/97

Vice President, OTC R&D

1/94 to 6/95

Vice President, Special Projects

4/93 to 12/93

Sr. Director, Technology Development

11/92 to 3/93

##### **Fulsz/Biovail Experience And Accomplishments**

- Developed business partnerships and launched products in more than eight countries, including USA, with licensing and supply agreements.
  - Partners include Otsuka-Pharmavite/USA, Abbott International Laboratories Columbia/Mexico, Beechline Healthcare/Ireland-UK, UK Forum, Pharma-Vicci/ Denmark, ConAgra/ USA, Dandy-Sakiz/ Turkey, CSM Leaf/Netherlands.
  - First year revenue exceeded with \$5.4 million development/licensing fees and \$6 million sales, with a retail value of more than \$30 million.
  - Planned new products and global expansion of existing products
- Associated with development of proprietary technology platforms leading to fast melt and easy chew pharmaceutical tablets, nougat soft chew, dry beverages, oral hygiene products, herbals and medicated confectionery and chewing gums, encapsulated ingredients for products such as Tums, Xylofresh and Nicorette Gum.
- Started manufacturing operations with limited capital and used success-based investment strategy to maintain a high rate of return.

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CAPRICORN PHARMA INC

PAGE 08/11

- Created new business culture, with focus on customer needs; product superiority; and speed of action
  - Customer focus: Product value proposition, therapeutic claims and cost
  - Product superiority: Quality; global thinking and planning;
  - Speed of Action: Faster to market with greater manufacturing cost effectiveness.

**Warner Lambert Co. Consumer Products R&D Center**  
**Director, Worldwide Technology Development**

1981 to 1982

Morris Plains, New Jersey

OTC Products, Confectionery delivery systems, Encapsulations, Chewing Gum Bases, Materials research. Developed key aspects of global brands such as Listrine, Hall's, Roloids, Trident, Dentyne, Clorets, Effident, and Remegel.

**Squibb/ LifeSavers Division**  
**Sr. Research Manager - R&D**

1978 to 1981

Port Chester, New York

Developed unique dosage forms and chewing gum bases.

**Philadelphia Chewing Gums Corporation**  
**Manager, R&D and Technical Services**

1973 to 1978

Havertown, PA.

**Warner Lambert Ltd. (India)**  
**Production Manager- Confections**

1971 to 1972

Hyderabad, India.

Managed production of a wide range of products, including the Hall's cough drop line and assorted gums and mints

**Indian Drugs and Pharmaceuticals Ltd.**  
**Senior Manager- Pharmaceutical Product Development**

1966 to 1970

Hyderabad, India.

## EDUCATION

MBA, Wharton School, University of Pennsylvania

1978

M.S. in Pharmaceutics, Andhra University, Vizag, India

1966

B.S. in Pharmacy, Andhra University, Vizag, India

1964

## PUBLICATIONS:

More than ninety U.S. Patents and more than three hundred international patents issued.

## ASSOCIATIONS:

American Association of Pharmaceutical Scientists  
 Controlled Release Society  
 Product Development and Management Association  
 Wharton Alumni Association  
 American Association of Cereal Chemists  
 Institute of Food Technologists

## PERSONAL:

Married with two daughters. U.S. Citizen. Interests include jogging and tennis.

**APPENDIX B****S. Rao CHERUKURI'S U.S. PATENTS**

6,589,556	Rapid-melt semi-solid compositions, methods of making same
6,555,145	Alternate encapsulation process and products produced therefrom
6,482,465	Positive hydration method of preparing confectionery and product therefrom
6,406,717	Rapid-melt semi-solid compositions, methods of making same
6,375,982	Rapid-melt semi-solid compositions, methods of making same
6,365,209	Confectionery compositions and methods of making
6,344,222	Medicated chewing gum delivery system for nicotine
6,224,939	Method and apparatus for forming an encapsulated product matrix
6,174,514	Breath Freshening chewing gum with encapsulations
6,132,797	Method of preparing mesomorphic sugar products
5,976,603	Fiber and vitamin-fortified drink composition and beverage
5,965,162	Process for forming chewable quickly dispersing multi-vitamin preparation
5,935,600	Process for forming chewable quickly dispersing comestible unit
5,895,664	Process for forming quickly dispersing comestible unit and product therefrom
5,876,506	Mesomorphic sugar and products therefrom
5,824,342	Flash flow formed solloid delivery systems
5,804,247	Positive hydration method of preparing confectionary and product therefrom
5,744,180	Comestibles containing stabilized highly odorous flavor component delivery
5,654,003	Process and apparatus for making tablets and tablets made therefrom
5,633,027	Confectioneries containing stabilized highly odorous flavor component delivery
5,587,198	Positive hydration method of preparing confectionery and product therefrom
5,587,172	Process for forming quickly dispersing comestible unit and product therefrom
5,582,855	Flash flow formed solloid delivery systems
5,556,652	Comestibles containing stabilized highly odorous flavor component delivery
5,549,917	Flash flow formed solloid delivery systems
5,503,862	Method of subjecting a protein-containing material to flash flow processing
5,456,932	Method of converting a feedstock to a shearform product and product thereof
5,284,659	Encapsulated flavor with bioadhesive character in pressed mints and confections
5,266,335	Microencapsulated flavoring agents and methods for preparing same
5,204,129	Method for preparing pulverized polydextrose which is substantially free of acids
5,110,608	Chewing gums having longer lasting sweetness
5,108,763	Microencapsulated high intensity sweetening agents having prolonged sweetness
5,106,632	Enhanced sweetness of acesulfame-K in edible compositions
5,087,460	Reduced-calorie confectionery coated chewing gum compositions
5,082,671	Low moisture sucralose sweetened chewing gum
5,080,910	Stabilized chlorodeoxysugar sweetening agents in powder form and methods
5,066,511	Method for preparing pulverized polydextrose which is substantially free of acids
5,064,658	Encapsulated synergistic sweetening agent compositions comprising aspartame
5,061,496	Stabilized chlorodeoxysugar sweetening agents in liquid medium and methods
5,059,429	Sucralose sweetened chewing gum



5,059,428	Synergistic sweetening compositions containing polydextrose chlorodeoxysugar
5,059,416	Zinc compound delivery system with improved taste and texture
5,057,328	Food acid delivery systems containing polyvinyl acetate
5,045,326	Non-staling aerated bubble gum
5,043,169	Stabilized Sweetener Composition
5,030,459	High impact mint flavor for high base chewing gum
5,023,093	Reduced calorie chewing gum base and compositions containing the same
5,013,716	Unpleasant taste masking compositions and methods for preparing same
5,009,893	Breath-freshening edible compositions of methol and a carboxamide
5,004,595	Multiple encapsulated flavor delivery system and method of preparation
4,983,405	Reduced and low-calorie sugar and sugarless chewing gum compositions
4,983,404	Controlled release flavor system and method of preparation
4,981,698	Multiple encapsulated sweetener delivery system and method of preparation
4,980,178	Reduced calorie center-filled chewing gum compositions
4,980,177	Reduced-calorie saliva stimulating chewing gum compositions and methods
4,971,806	Multi-layered chewing gum composition having different rates of flavor release
4,971,797	Stabilized sucralose comple
4,971,787	Antacid chewing gum
4,961,935	Sugarless, substantially anhydrous chewing gum compositions and methods
4,954,353	Anhydrous chewing gum with improved stability
4,959,225	Synergistic sweetening compositions containing chlorodeoxysugars and maltitol
4,933,190	Multiple encapsulated sweetener delivery system
4,933,189	Chewing gum having longer lasting sweetness
4,933,188	Chewing gum compositions with improved physical stability
4,931,293	Food acid delivery systems containing polyvinyl acetate
4,915,958	High-base gum composition with extended flavor release
4,900,563	Fructose sweetened chewing gum compositions
4,872,884	Reduced calorie chewing gum base and compositions containing the same
4,853,212	Reduced base content chewing gum compositions having anesthetic properties
4,839,184	Stable sweetener delivery system for use with cinnamon flavors
4,832,962	Chewing gum and confectionery compositions containing a soy flavor enhancer
4,822,597	Anesthetic-containing chewing gum compositions
4,816,265	Sweetener delivery systems containing polyvinyl acetate
4,803,082	Flavor and sweetness enhancement delivery systems and method of preparation
4,794,003	Polyvinylacetate bubble gum base composition
4,765,991	Reduced calorie chewing gums and method
4,753,805	Tabletted chewing gum composition and method of preparation
4,724,151	Chewing gum compositions having prolonged breath-freshening
4,722,845	Stable cinnamon-flavored chewing gum composition
4,721,620	Polyvinylacetate bubble gum base composition
4,590,075	Elastomer encapsulation of flavors and sweeteners, long lasting flavored chewing
4,587,125	Non-staling chewing gum compositions and improved method of preparation
4,581,234	Non-staling, substantially moistureless chewing gum compositions
4,579,738	Non-staling chewing gum compositions and improved method of preparation
4,518,615	Non-adhesive chewing gum base composition
4,497,832	Chewing gum composition having enhanced flavor-sweetness

4,490,395 Chewing gum with improved stability  
4,409,244 Chewing gum containing fructose syrup  
4,371,549 Stable liquid red beet color and chewing gum containing same  
4,352,825 Coextruded chewing gum containing a soft core portion  
4,352,823 Coextruded chewing gum containing a soft non-SBR gum core portion  
4,352,822 Gum base, chewing gum containing same and method  
4,317,838 Method for applying sugarless coating to chewing gum and confections  
4,316,915 Center-filled chewing gums  
4,271,199 Sugar-containing chewing gum having smooth texture and long-lasting sweetness  
4,271,198 Chewing gum having a soft texture  
4,271,197 Chewing gum containing sugar substitute  
4,250,195 Method for applying soft flexible sugar coating to fresh chewing gum  
4,238,510 Sugarless coating for chewing gum and confections and method